

## MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
Center for Biologics Evaluation and ResearchDATE: **AUG 25 1998**FROM: Sharon O'Callaghan, CSO,<sup>doc</sup>  
Division of Inspections and Surveillance (HFM-650)

SUBJECT: Error and Accident Reports - Summary for Third Quarter FY98

TO: Acting Director, Division of Inspections and Surveillance (HFM-650) *JS*

Between April 1, 1998 and June 30, 1998, the Division of Inspections and Surveillance received 1,457 error and accident reports from the American Red Cross (ARC), 1,494 error and accident reports from non-ARC licensed blood establishments, 81 error and accident reports from unlicensed registered blood establishments, 271 error and accident reports from plasma centers, 2 reports from transfusion services, 7 reports from blood derivative manufacturers, 6 reports from in-vitro diagnostic manufacturers, 1 report from a vaccine manufacturer, 2 reports from allergenic manufacturers, and 1 report from a therapeutic manufacturer. A total of 3,322 error and accident reports were received. There were 445 (13.4%) reports forwarded to the District Offices for follow-up and evaluation as potential recall situations. Based on the information submitted in the error and accident reports, 214 (6.4%) reports did not appear to meet the threshold for reporting, i.e., products were not made available for distribution or the safety, purity, or potency of a product was not affected.

Between October 1, 1997 and June 30, 1998, the Division of Inspections and Surveillance received a total of 9,682 error and accident reports. There were 1233 (12.7%) reports forwarded to the District Offices for follow-up and evaluation as potential recall situations. Based on the information submitted in the error and accident reports, 666 (6.9%) reports did not appear to meet the threshold for reporting, i.e., products were not made available for distribution or the safety, purity, or potency of a product was not affected.

Attached are tables and charts that identify the types of reportable and non-reportable errors and accidents submitted. Examples of errors and accidents in the top three categories are provided. A table and graphs representing reportable errors and accidents are also provided that illustrate the distribution of the reporting time, i.e., time from the date the error or accident was discovered to the date CBER received the report.

## Attachments

- 1 - Table - Total Error/Accident Reports  
All Reporting Establishments
- 2 - Tables - Types of Errors/Accidents  
Blood and Plasma Establishments  
Total Reports, Potential Recalls
- 3 - Tables - Types of Errors/Accidents  
Non-Blood Manufacturers
- 4 - Pie charts - All Blood and Plasma Establishments  
Total Reports
- 5 - Pie charts - All Blood and Plasma Establishments  
Potential Recalls
- 6 - Pie charts - Types of Errors/Accidents  
ARC
- 7 - Pie charts - Types of Errors/Accidents  
Non-ARC Licensed Blood Banks
- 8 - Pie charts - Types of Errors/Accidents  
Unlicensed Blood Banks
- 9 - Pie charts - Types of Errors/Accidents  
Plasma Centers
- 10 - Pie charts - Types of Errors/Accidents  
Blood Banks, Plasma Centers
- 11 - Pie charts - Types of Errors/Accidents  
Licensed Blood Banks, Unlicensed Blood Banks, Plasma Centers
- 12 - Tables - Types of Errors/Accidents  
Blood and Plasma Establishments  
Non-Reportable, Reportable, Total
- 13 - Pie charts - Types of Errors/Accidents  
Reportable E/A's
- 14 - List - Top Three Categories of Reportable Errors/Accidents  
Year-To-Date
- 15 - Pie charts - Types of Errors/Accidents  
Non-Reportable E/A's
- 16 - List - Top Three Categories of Non-Reportable Errors/Accidents  
Year-To-Date
- 17 - Tables - Reporting Time
- 18 - Line graphs - Reporting Time  
All Reporting Blood Establishments
- 19 - Line graphs - Reporting Time  
ARC
- 20 - Line graphs - Reporting Time  
Non-ARC Licensed Blood Banks
- 21 - Line graphs - Reporting Time  
Unlicensed Blood Banks
- 22 - Line graphs - Reporting Time  
Plasma Centers
- 23 - Line graphs - Reporting Time  
All Licensed Blood Establishments

**THIRD QUARTER - FY98  
ALL REPORTING ESTABLISHMENTS**

	TOTAL REPORTS RECEIVED		POTENTIAL RECALLS	
	THIRD QUARTER	YEAR-TO-DATE	THIRD QUARTER	YEAR-TO-DATE
AMERICAN RED CROSS	1457	4315	115	404
NON-ARC LICENSED BLOOD BANKS	1494	4333	304	744
UNLICENSED BLOOD BANKS	81	159	8	14
TRANSFUSION SERVICES	2	12	0	0
PLASMA CENTERS	271	834	14	64
BLOOD DERIVATIVE MANUFACTURER	7	11	0	0
IN-VITRO DIAGNOSTIC MANUFACTURER	6	10	2	5
VACCINE MANUFACTURER	1	3	0	0
ALLERGENICS MANUFACTURER	2	2	2	2
THERAPEUTICS MANUFACTURER	1	3	0	0
<b>TOTAL</b>	<b>3322</b>		<b>445</b>	
<b>TOTAL - YEAR-TO-DATE 10/1/97 - 6/30/98</b>		<b>9682</b>		<b>1233</b>

The following tables and pie charts show the type of errors and accidents reported:

**THIRD QUARTER - FY98  
BLOOD AND PLASMA ESTABLISHMENTS**

**TOTAL ERRORS AND ACCIDENTS**

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	29	40	8	0	0	77	2.3%
VIRAL TESTING	7	22	1	0	1	31	0.9%
COLLECTION	17	15	0	0	1	33	1.0%
COMPONENT PREPARATION	22	30	0	1	0	53	1.6%
LABELING	148	154	12	0	7	321	9.7%
DONOR SCREENING	90	131	8	0	19	248	7.5%
DONOR DEFERRAL	6	12	2	0	2	22	0.7%
POST DONATION INFO	977	804	18	0	215	2014	60.9%
STORAGE/DISTRIBUTION	125	244	22	1	9	401	12.1%
MISCELLANEOUS	36	42	10	0	17	105	3.2%
<b>TOTAL</b>	<b>1457</b>	<b>1494</b>	<b>81</b>	<b>2</b>	<b>271</b>	<b>3305</b>	<b>100%</b>

**POTENTIAL RECALLS**

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	0	1	0	0	0	1	0.2%
VIRAL TESTING	2	16	0	0	0	18	4.1%
COLLECTION	5	8	0	0	0	13	2.9%
COMPONENT PREPARATION	12	18	0	0	0	30	6.8%
LABELING	12	30	1	0	2	45	10.2%
DONOR SCREENING	45	79	3	0	8	135	30.6%
DONOR DEFERRAL	4	9	2	0	1	16	3.6%
POST DONATION INFO	9	5	0	0	0	14	3.2%
STORAGE/DISTRIBUTION	26	138	2	0	3	169	38.3%
MISCELLANEOUS	0	0	0	0	0	0	0.0%
<b>TOTAL</b>	<b>115</b>	<b>304</b>	<b>8</b>	<b>0</b>	<b>14</b>	<b>441</b>	<b>100%</b>

THIRD QUARTER - FY98  
NON-BLOOD MAUFACTURERS

TYPE OF ERROR/ACCIDENT	IN-VITRO DIAGNOSTIC		DERIVATIVE		VACCINE		THERAPEUTIC		ALLERGENIC		TOTAL		RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
LABELING	3	1	1	0	1	0	0	0	2	2	7	41.2%	3	75.0%
STORAGE/DISTRIBUTION	2	0	1	0	0	0	0	0	0	0	3	17.6%	0	0.0%
STERILITY COMPROMISED	0	0	0	0	0	0	1	0	0	0	1	5.9%	0	0.0%
DECREASE IN POTENCY	1	1	1	0	0	0	0	0	0	0	2	11.8%	1	25.0%
SOURCE MATERIAL WITHDRAWN DUE TO CJD RISK	0	0	3	0	0	0	0	0	0	0	3	17.6%	0	0.0%
NOT REPORTABLE-PRODUCT QUALITY NOT AFFECTED	0	0	1	0	0	0	0	0	0	0	1	5.9%	0	0.0%
<b>TOTAL</b>	<b>6</b>	<b>2</b>	<b>7</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>2</b>	<b>17</b>	<b>100%</b>	<b>4</b>	<b>100%</b>

YEAR-TO-DATE - FY98  
NON-BLOOD MAUFACTURERS

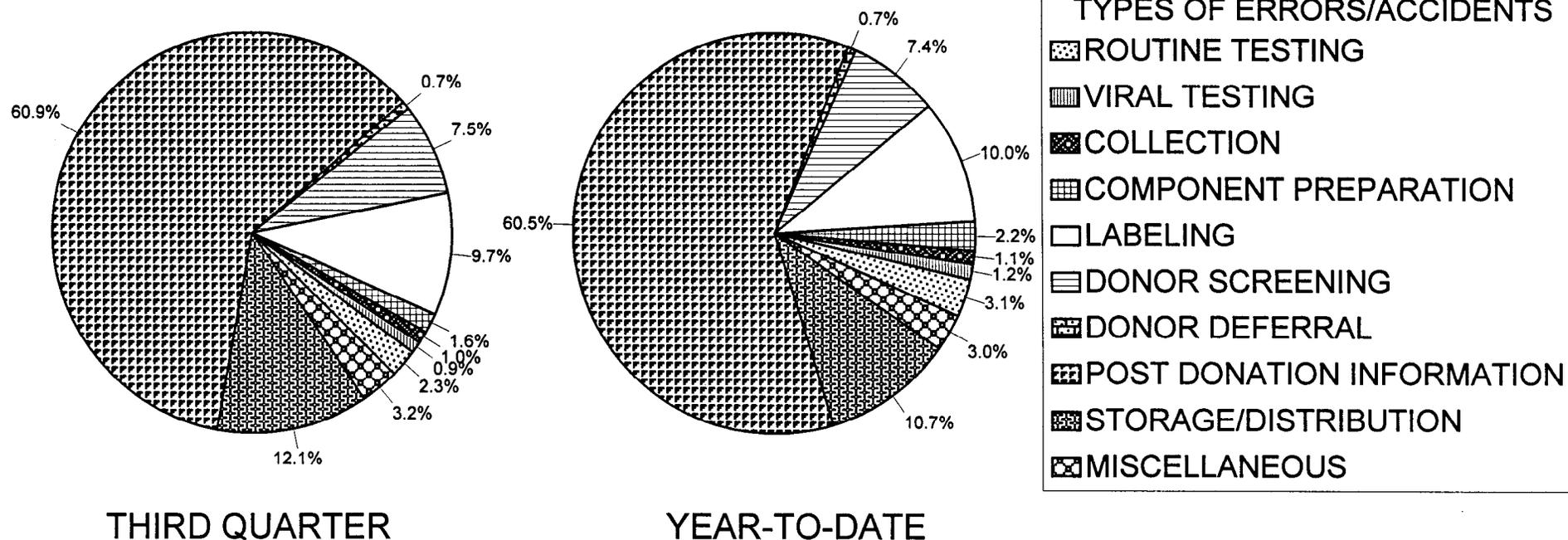
TYPE OF ERROR/ACCIDENT	IN-VITRO DIAGNOSTIC		DERIVATIVE		VACCINE		THERAPEUTIC		ALLERGENIC		TOTAL		RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
LABELING	4	2	1	0	2	0	0	0	2	2	9	31.0%	4	57.1%
STORAGE/DISTRIBUTION	2	0	2	0	0	0	1	0	0	0	5	17.2%	0	0.0%
STERILITY COMPROMISED	0	0	1	0	0	0	2	0	0	0	3	10.3%	0	0.0%
DECREASE IN POTENCY	3	3	1	0	0	0	0	0	0	0	4	13.8%	3	42.9%
SOURCE MATERIAL WITHDRAWN DUE TO CJD RISK	0	0	5	0	0	0	0	0	0	0	5	17.2%	0	0.0%
UNAPPROVED SEED PASSAGE USED	0	0	0	0	1	0	0	0	0	0	1	3.4%	0	0.0%
NOT REPORTABLE-PRODUCTS NOT MADE AVAILABLE	1	0	0	0	0	0	0	0	0	0	1	3.4%	0	0.0%
NOT REPORTABLE-PRODUCT QUALITY NOT AFFECTED	0	0	1	0	0	0	0	0	0	0	1	3.4%	0	0.0%
<b>TOTAL</b>	<b>10</b>	<b>5</b>	<b>11</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>2</b>	<b>2</b>	<b>29</b>	<b>100%</b>	<b>7</b>	<b>100%</b>

# ERROR AND ACCIDENT REPORTS

## ALL BLOOD AND PLASMA ESTABLISHMENTS

### TOTAL REPORTS

### FY98



REPORTS RECEIVED THIRD QUARTER (4/1/98 - 6/30/98) = 3305

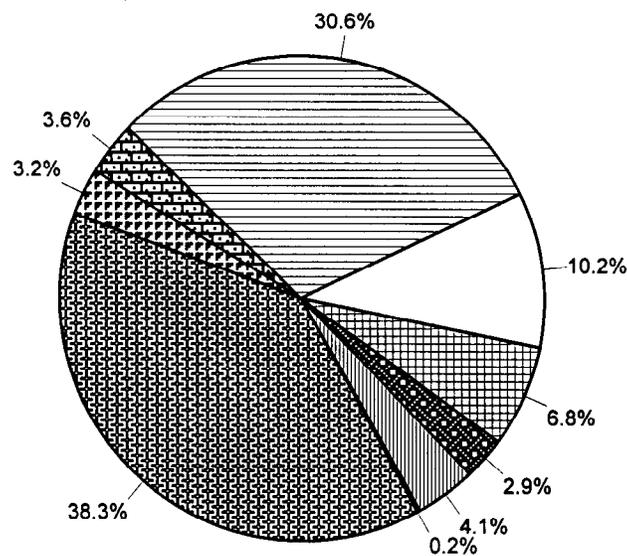
REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 6/30/98) = 9653

# ERROR AND ACCIDENT REPORTS

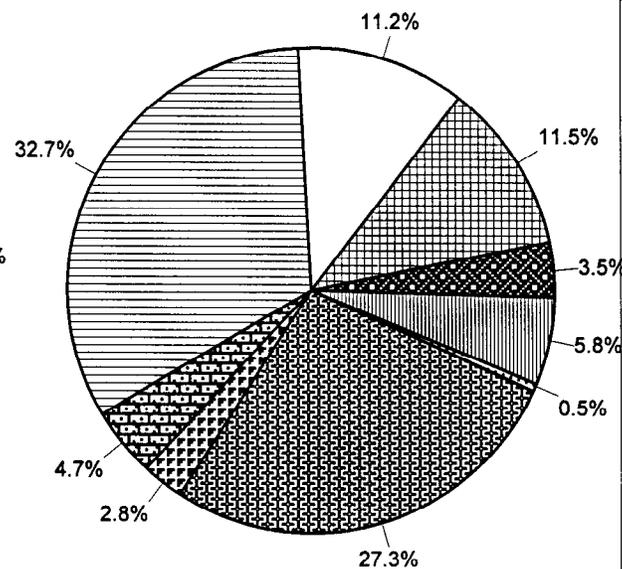
## ALL BLOOD AND PLASMA ESTABLISHMENTS

### POTENTIAL RECALLS

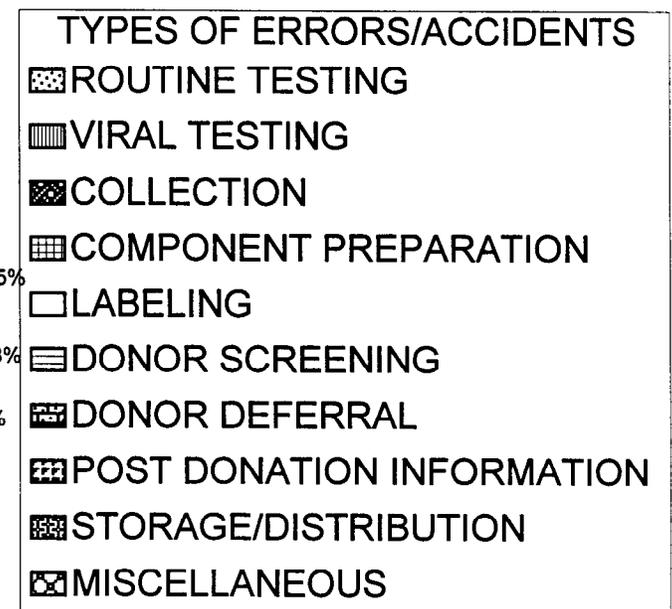
### FY98



THIRD QUARTER



YEAR-TO-DATE

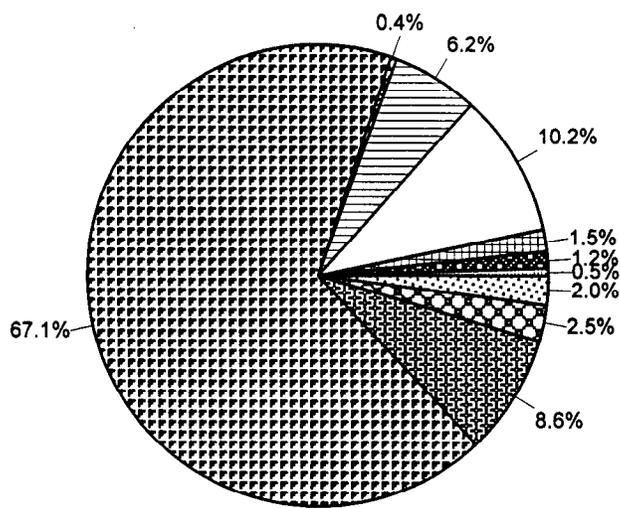


REPORTS RECEIVED THIRD QUARTER (4/1/98 - 6/30/98) = 441  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 6/30/98) = 1226

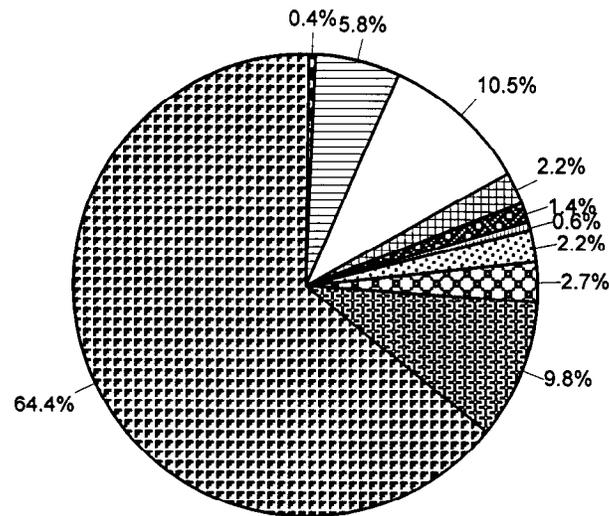
# ERROR AND ACCIDENT REPORTS

## AMERICAN RED CROSS

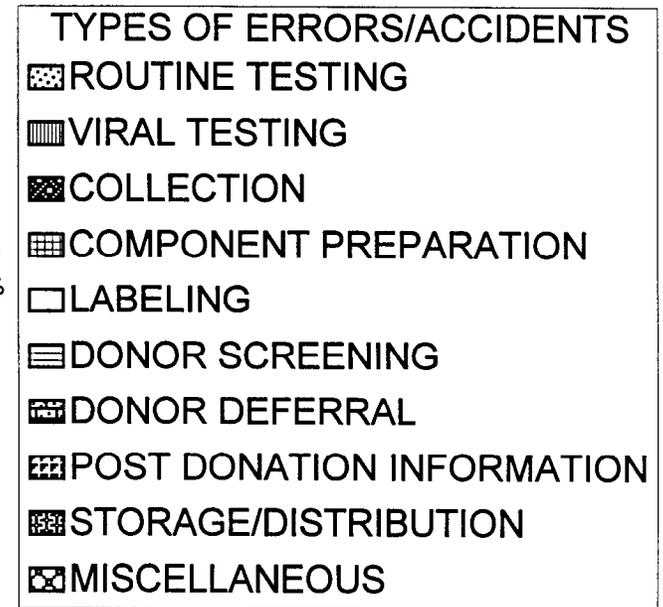
### FY98



THIRD QUARTER



YEAR-TO-DATE

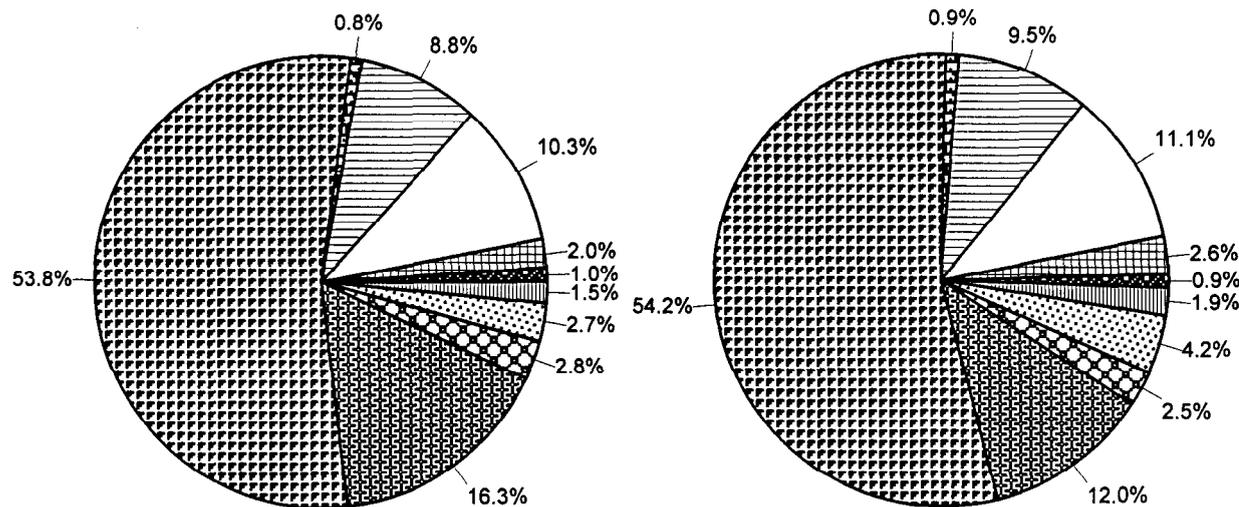


REPORTS RECEIVED THIRD QUARTER (4/1/98 - 6/30/98) = 1457  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 6/30/98) = 4315

# ERROR AND ACCIDENT REPORTS

## NON-ARC LICENSED BLOOD BANKS

### FY98



THIRD QUARTER

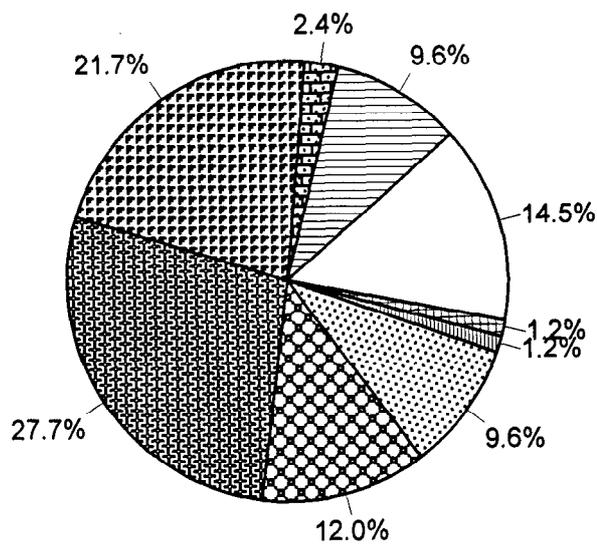
YEAR-TO-DATE

REPORTS RECEIVED THIRD QUARTER (4/1/98 - 6/30/98) = 1494  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 6/30/98) = 4333

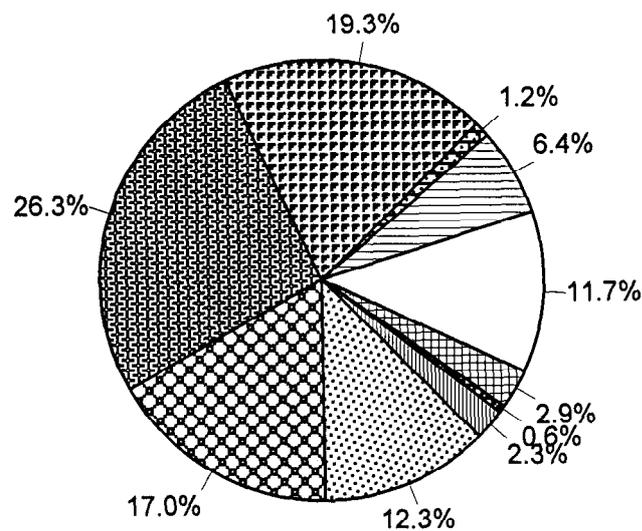
# ERROR AND ACCIDENT REPORTS

## UNLICENSED BLOOD BANKS

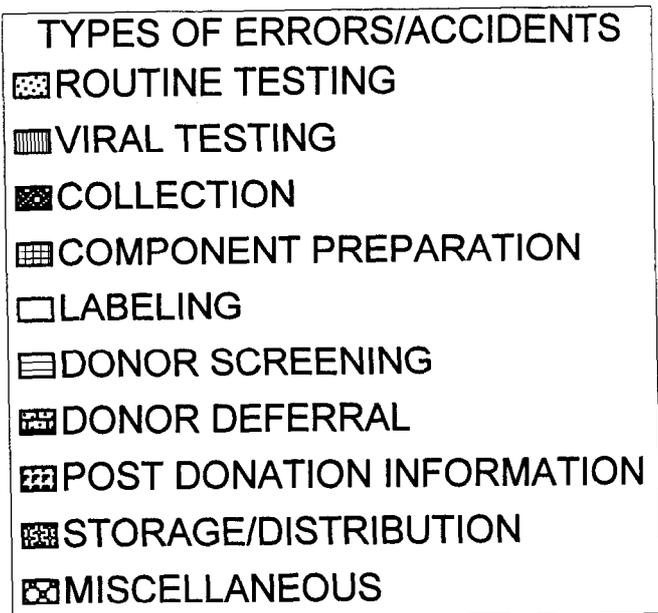
### FY98



THIRD QUARTER



YEAR-TO-DATE

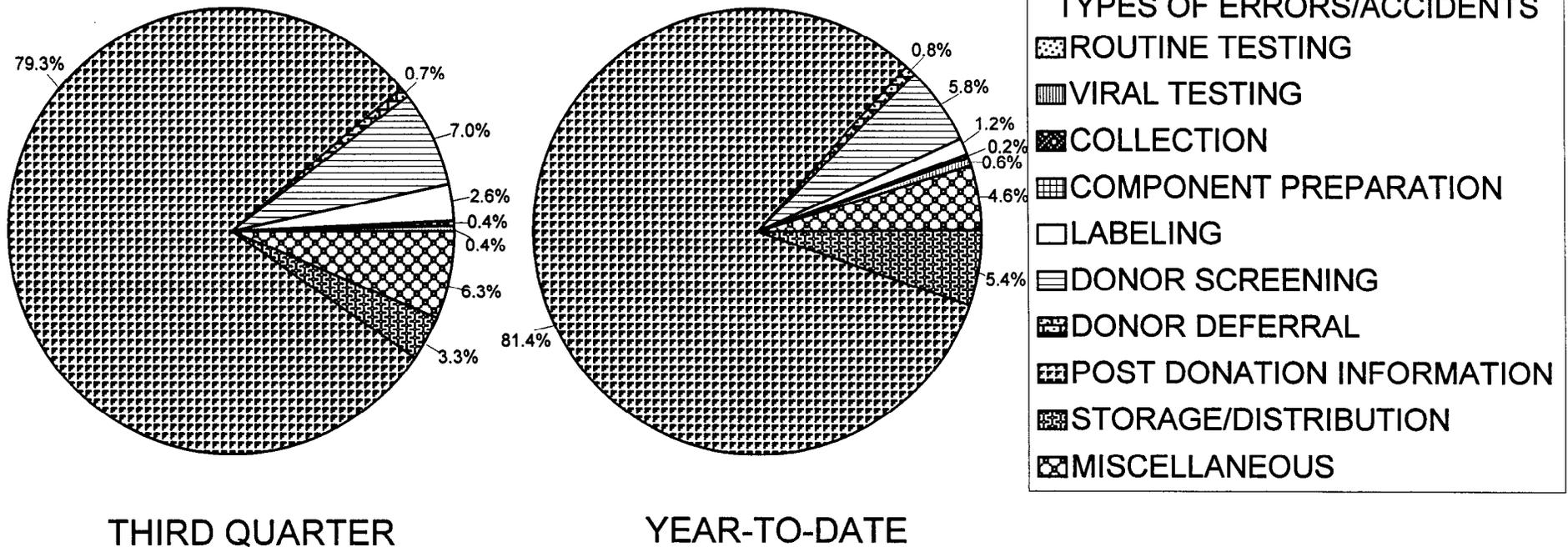


REPORTS RECEIVED THIRD QUARTER (4/1/98 - 6/30/98) = 83 (2 REPORTS - TRANSFUSION SERVICES)  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 6/30/98) = 171 (12 REPORTS - TRANSFUSION SERVICES)

# ERROR AND ACCIDENT REPORTS

## PLASMA CENTERS

### FY98



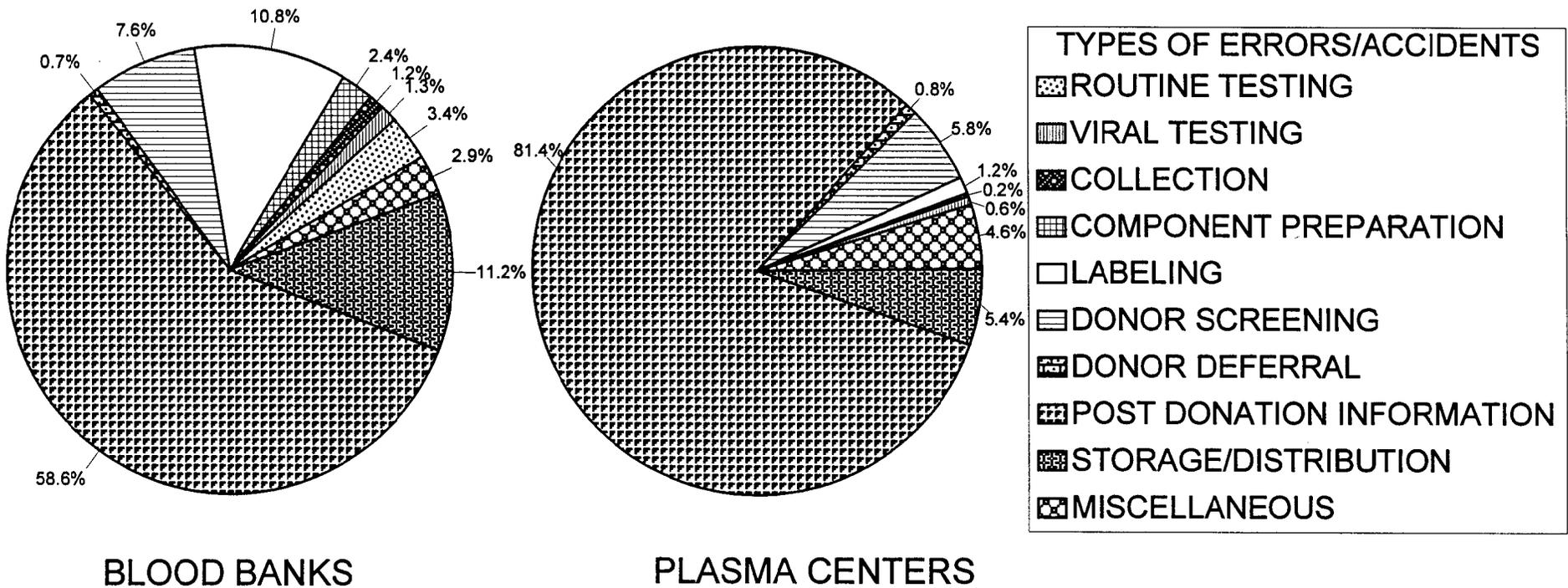
REPORTS RECEIVED THIRD QUARTER (4/1/98 - 6/30/98) = 271

REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 6/30/98) = 834

# ERROR AND ACCIDENT REPORTS

## BLOOD BANKS VERSUS PLASMA CENTERS

### FY98 YEAR-TO-DATE

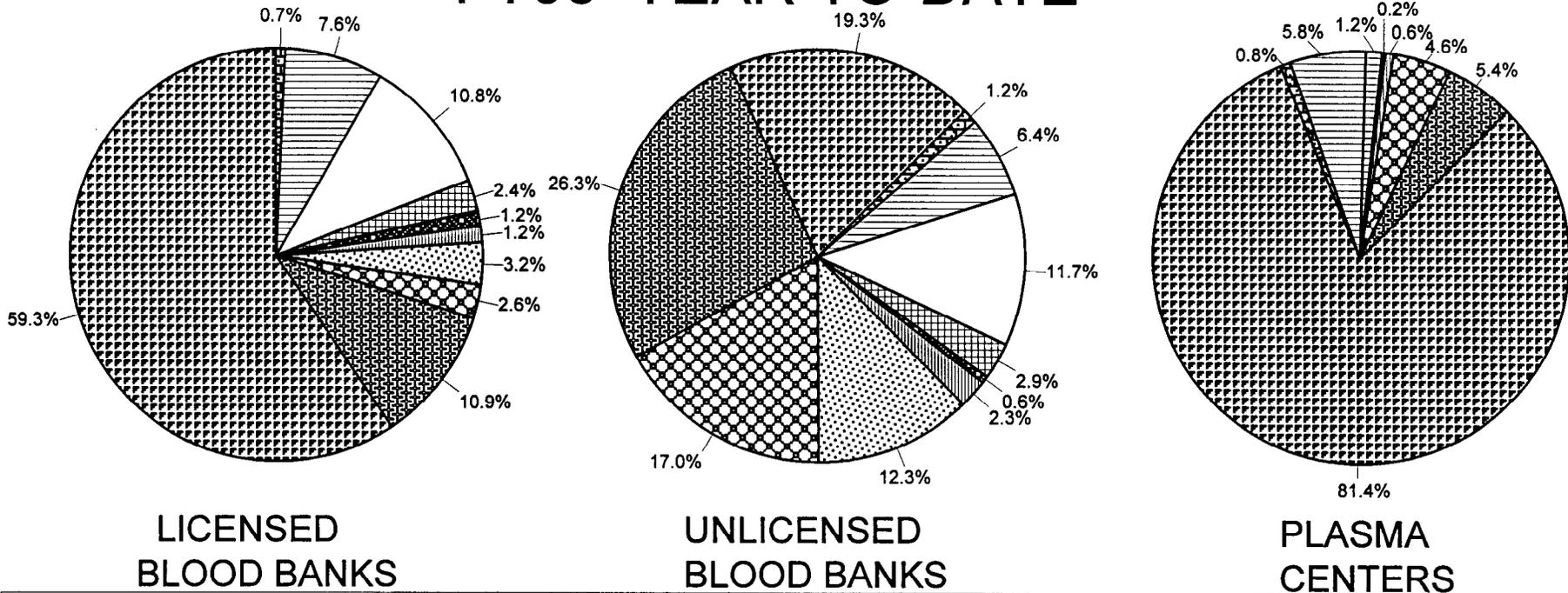


REPORTS RECEIVED 10/1/97 - 6/30/98  
 BLOOD BANKS = 8819  
 PLASMA CENTERS = 834

# ERROR AND ACCIDENT REPORTS

## BLOOD BANKS VERSUS PLASMA CENTERS

### FY98 YEAR-TO-DATE



TYPES OF ERRORS/ACCIDENTS

ROUTINE TESTING	VIRAL TESTING	COLLECTION
COMPONENT PREPARATION	LABELING	DONOR SCREENING
DONOR DEFERRAL	POST DONATION INFORMATION	STORAGE/DISTRIBUTION
MISCELLANEOUS		

REPORTS RECEIVED 10/1/97 - 6/30/98

LICENSED BLOOD BANKS = 8648

UNLICENSED BLOOD BANKS = 171

PLASMA CENTERS = 834

**THIRD QUARTER - FY98  
BLOOD AND PLASMA ESTABLISHMENTS**

TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	2	75	77	2.6%
VIRAL TESTING	2	29	31	6.5%
COLLECTION	8	25	33	24.2%
COMPONENT PREPARATION	3	50	53	5.7%
LABELING	51	270	321	15.9%
DONOR SCREENING	31	217	248	12.5%
DONOR DEFERRAL	1	21	22	4.5%
POST DONATION INFORMATION	11	2003	2014	0.5%
STORAGE/DISTRIBUTION	8	393	401	2.0%
MISCELLANEOUS	96	9	105	91.4%
<b>TOTAL</b>	<b>213</b>	<b>3092</b>	<b>3305</b>	<b>6.4%</b>

%NON-REPORTABLE = Non-Reportable/Total for each category

**FY98 - YEAR-TO-DATE  
BLOOD AND PLASMA ESTABLISHMENTS**

TYPE OF ERROR/ACCIDENT	NON-REPORTABLE	REPORTABLE	TOTAL	%NON-REPORTABLE
ROUTINE TESTING	2	296	298	0.7%
VIRAL TESTING	9	107	116	7.8%
COLLECTION	30	74	104	28.8%
COMPONENT PREPARATION	5	211	216	2.3%
LABELING	144	820	964	14.9%
DONOR SCREENING	87	632	719	12.1%
DONOR DEFERRAL	2	66	68	2.9%
POST DONATION INFORMATION	42	5801	5843	0.7%
STORAGE/DISTRIBUTION	74	957	1031	7.2%
MISCELLANEOUS	269	25	294	91.5%
<b>TOTAL</b>	<b>664</b>	<b>8989</b>	<b>9653</b>	<b>6.9%</b>

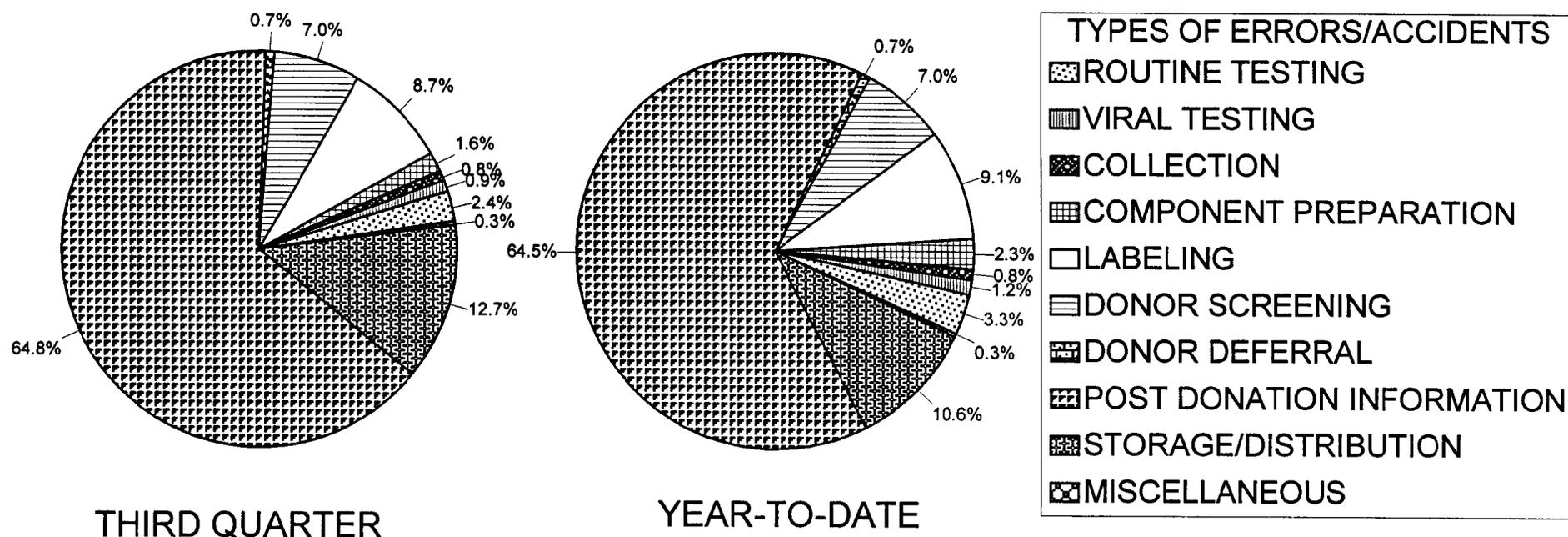
%NON-REPORTABLE = Non-Reportable/Total for each category

# ERROR AND ACCIDENT REPORTS

## ALL BLOOD AND PLASMA ESTABLISHMENTS

### REPORTABLE ERRORS/ACCIDENTS

## FY98



REPORTS RECEIVED THIRD QUARTER (4/1/98 - 6/30/98) = 3092  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 6/30/98) = 8989

**FY98 YEAR-TO-DATE**

REPORTABLE ERRORS/ACCIDENTS - 8989 (93.1% of total reports)

Top Three Categories of Errors/Accidents:

Post Donation Information - 5801 (64.5% of reportables)

*\*Examples:*

Information provided post donation:

- Donor traveled to a malarial endemic area
- Donor received tattoo, earpiercing, needlestick, or transfusion
- Donor became ill after donation,  
**not related to hepatitis, HIV, HTLV-I, sexually transmitted diseases or cold/flu symptoms**
- Donor had a history of cancer

Storage/Distribution - 957 (10.6% of reportables)

*\*Examples:*

- Release of product that contained clots or would not flow through a filter
- Product was shipped or stored at incorrect temperature
- Failure to quarantine a unit that was designated to be quarantined due to unsuitable medical history
- Failure to quarantine a unit that was designated to be quarantined due to incorrect, incomplete, or positive testing

Labeling - 820 (9.1% of reportables)

*\*Examples:*

- Additional information on autologous unit incorrect or missing, e.g., name, social security number, or date of birth
- Product labeled with extended expiration date
- Incorrect product label

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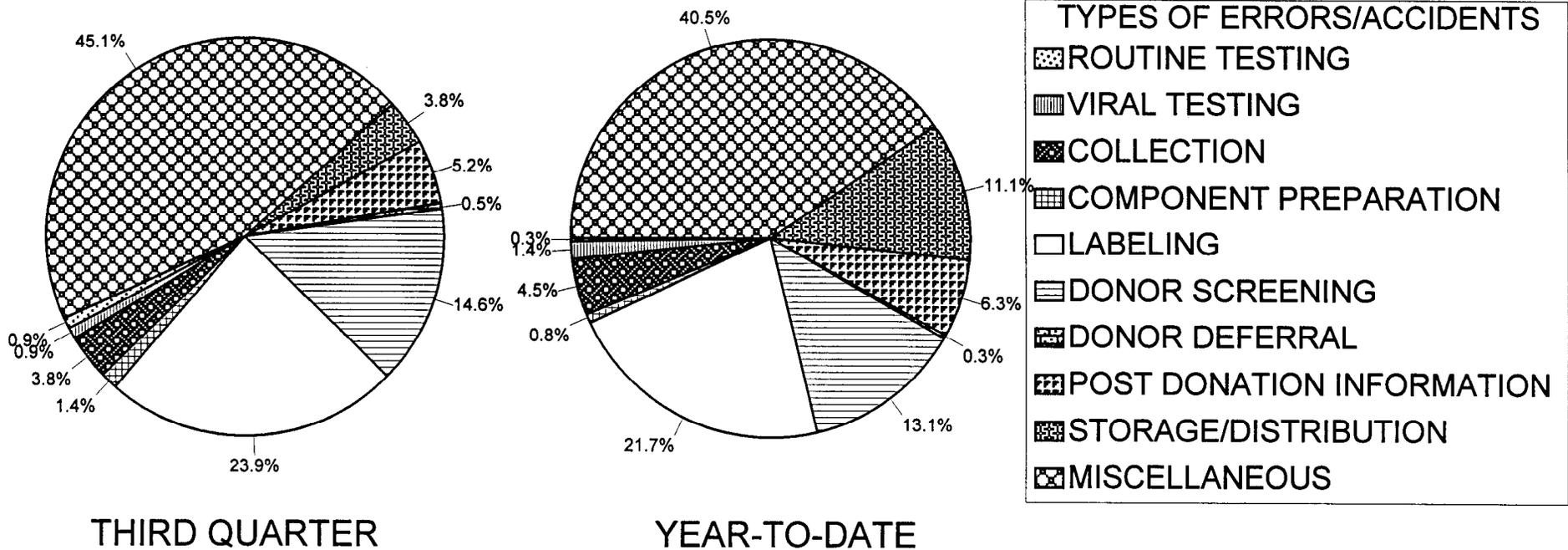
\*Examples of errors and accidents represent at least 50% of reports in each category.

# ERROR AND ACCIDENT REPORTS

## ALL BLOOD AND PLASMA ESTABLISHMENTS

### NON-REPORTABLE ERRORS/ACCIDENTS

#### FY98



REPORTS RECEIVED THIRD QUARTER (4/1/98 - 6/30/98) = 213  
 REPORTS RECEIVED YEAR-TO-DATE (10/1/97 - 6/30/98) = 664

**FY98 YEAR-TO-DATE**

NON-REPORTABLE ERRORS/ACCIDENTS - 664 (6.9% of total reports)

Top Three Categories of Errors/Accidents:

Miscellaneous 269 ( 40.5% of non-reportables)

*\*Examples:*

- No products made available for distribution
- Destruction records incomplete, final disposition of product unknown  
(documentation indicates unit was suitable at time of distribution)
- Recall procedures not followed (e.g., recall not performed within appropriate time)
- Recordkeeping error/accident - record is incorrect or not reviewed, testing and labeling acceptable

Labeling - 144 (21.7% of non-reportables)

*\*Examples:*

- Unit labeled with incorrect weight, volume, collection date, or facility identifiers; unit acceptable
- Unit missing label for ABO/Rh, product, or expiration date
- Unit labeled with a shortened expiration date

Donor Suitability - 87 (13.1% of non-reportables)

*\*Example:*

- Donor did not meet acceptance criteria for time interval between donations
- Donor did not meet acceptance criteria for age
- Donor did not meet acceptance criteria for total protein or SPE

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\*Examples of errors and accidents represent at least 50% of reports in each category.

The following table and graphs show the time periods in which the reports were received by CBER. The evaluation of timeliness is limited to only reports that met the threshold for reporting.

**ERROR AND ACCIDENT REPORTS  
THIRD QUARTER - FY98**

**NUMBER OF DAYS FROM DATE E/A DISCOVERED TO FDA RECEIVED  
BLOOD ESTABLISHMENTS**

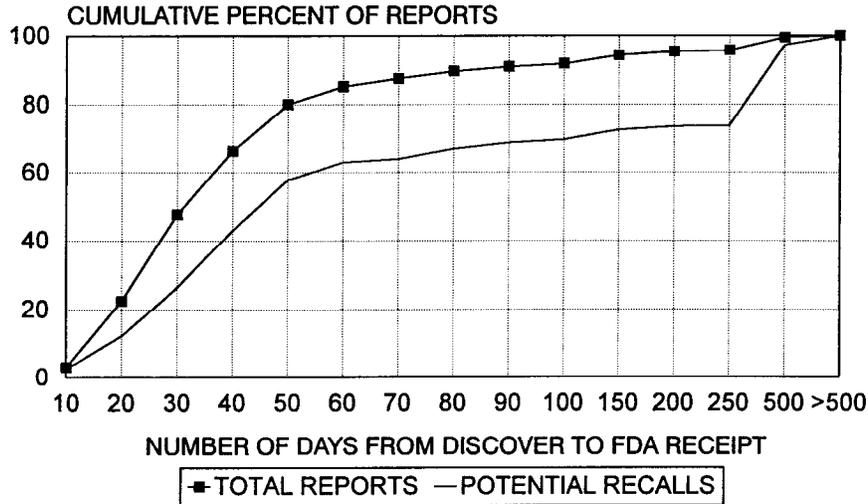
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	15	9	11	14
25%	21	22	20	14	21
50%	30	34	33	33	31
75%	39	66	65	61	46
90%	48	175	114	134	83
# REPORTS	1370	1396	69	257	3092
RANGE	5-506	4-1132	5-585	3-559	3-1132

**ERROR AND ACCIDENT REPORTS  
RECEIVED 10/1/97 - 6/30/98**

**NUMBER OF DAYS FROM DATE E/A DISCOVERED TO FDA RECEIVED  
BLOOD ESTABLISHMENTS**

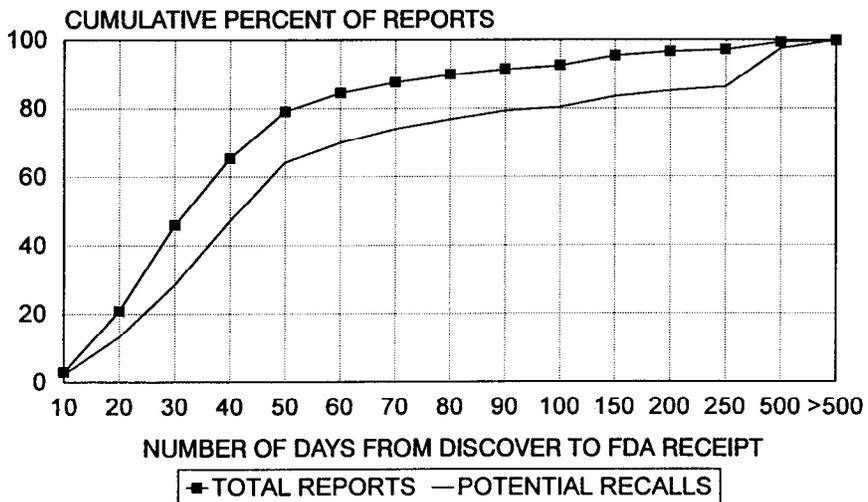
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	14	9	10	15
25%	22	21	14	18	21
50%	30	35	27	37	32
75%	39	61	53	78	47
90%	48	117	98	145	81
# REPORTS	4016	4037	134	801	8988
RANGE	5-706	4-1132	5-727	3-559	3-1132

## ERROR AND ACCIDENT REPORTS REPORTING TIME ALL REPORTING BLOOD ESTABLISHMENTS THIRD QUARTER FY98



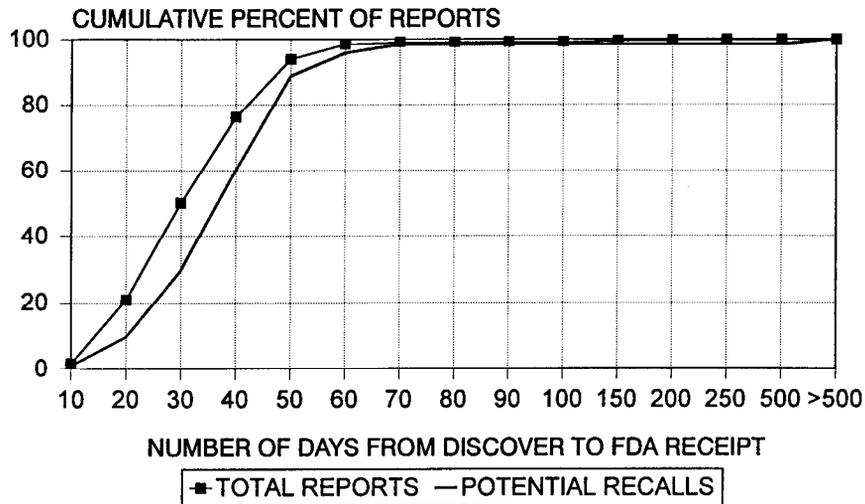
TOTAL REPORTS = 3092  
POTENTIAL RECALLS = 441

## ERROR AND ACCIDENT REPORTS REPORTING TIME ALL REPORTING BLOOD ESTABLISHMENTS YEAR -TO-DATE FY98



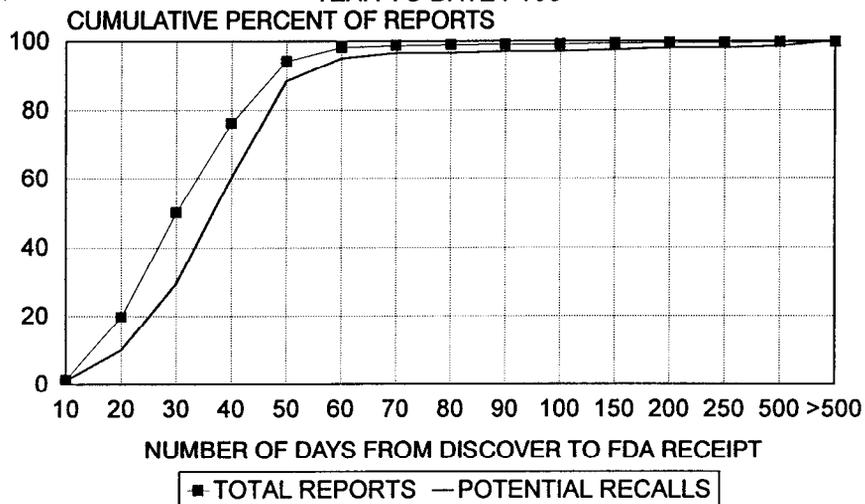
TOTAL REPORTS = 8988  
POTENTIAL RECALLS = 1225

## ERROR AND ACCIDENT REPORTS REPORTING TIME AMERICAN RED CROSS THIRD QUARTER FY98



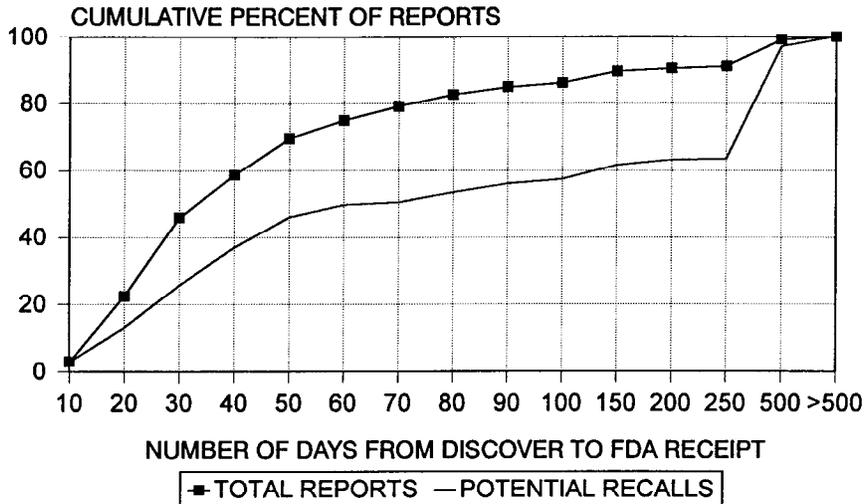
TOTAL REPORTS = 1370  
POTENTIAL RECALLS = 115

## ERROR AND ACCIDENT REPORTS REPORTING TIME AMERICAN RED CROSS YEAR-TO-DATE FY98



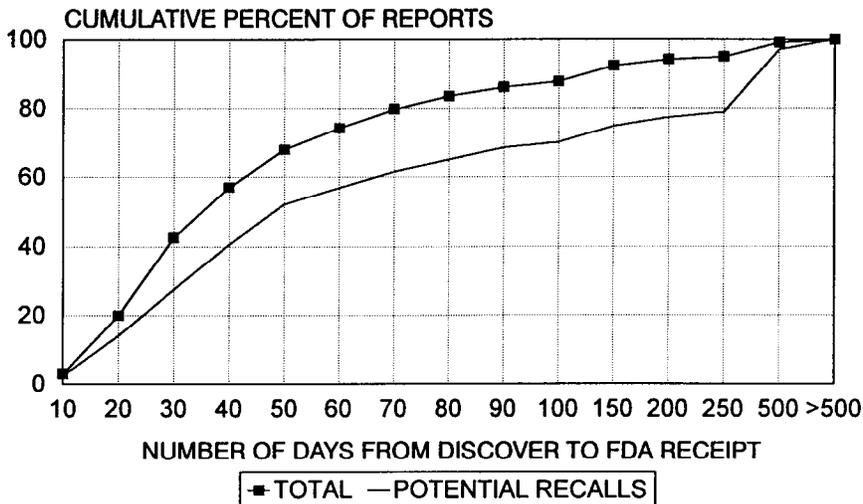
TOTAL REPORTS = 4016  
POTENTIAL RECALLS = 404

## ERROR AND ACCIDENT REPORTS REPORTING TIME NON-ARC LICENSED BLOOD BANKS THIRD QUARTER FY98



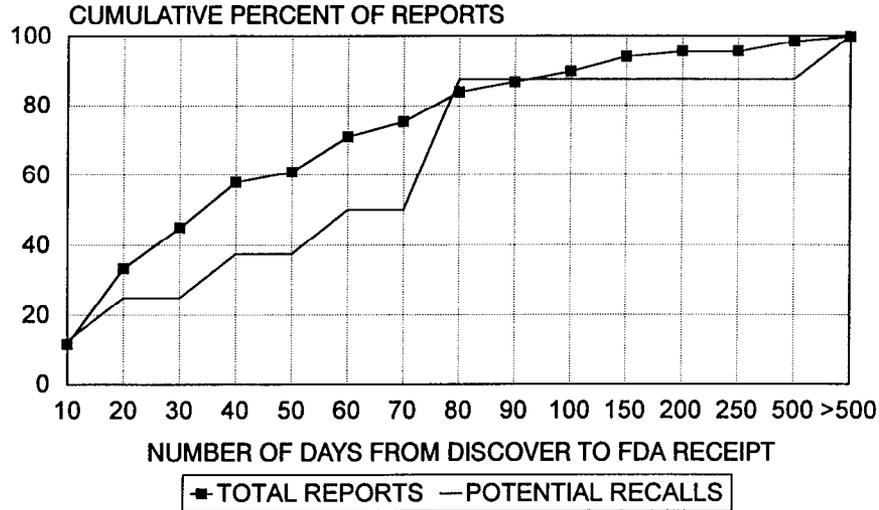
TOTAL REPORTS = 1396  
POTENTIAL RECALLS = 304

## ERROR AND ACCIDENT REPORTS REPORTING TIME NON-ARC LICENSED BLOOD BANKS YEAR-TO-DATE FY98



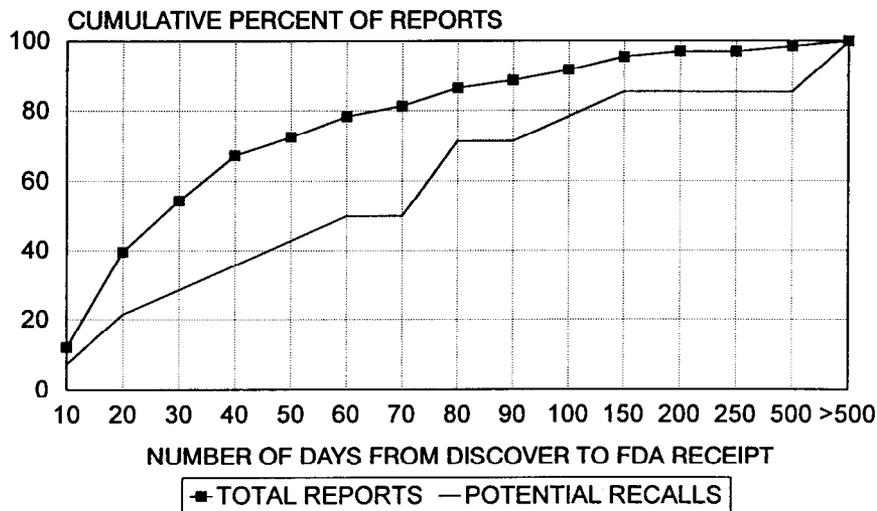
TOTAL REPORTS = 4037  
POTENTIAL RECALLS = 743

## ERROR AND ACCIDENT REPORTS REPORTING TIME UNLICENSED BLOOD BANKS THIRD QUARTER FY98



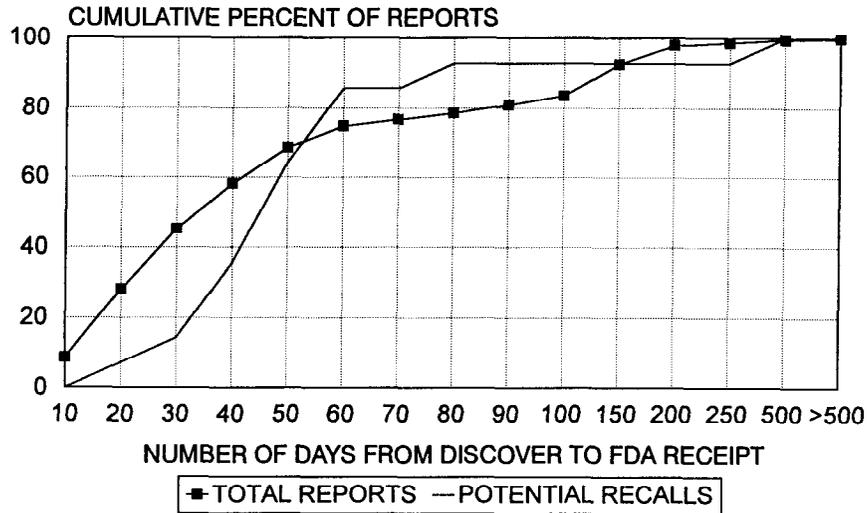
TOTAL REPORTS = 69  
POTENTIAL RECALLS = 8

## ERROR AND ACCIDENT REPORTS REPORTING TIME UNLICENSED BLOOD BANKS YEAR-TO-DATE FY98



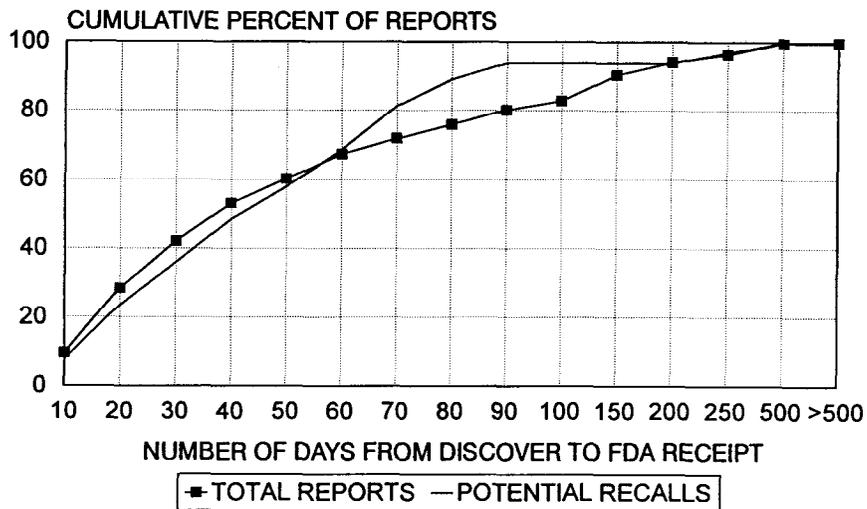
TOTAL REPORTS = 134  
POTENTIAL RECALLS = 14

## ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS THIRD QUARTER FY98



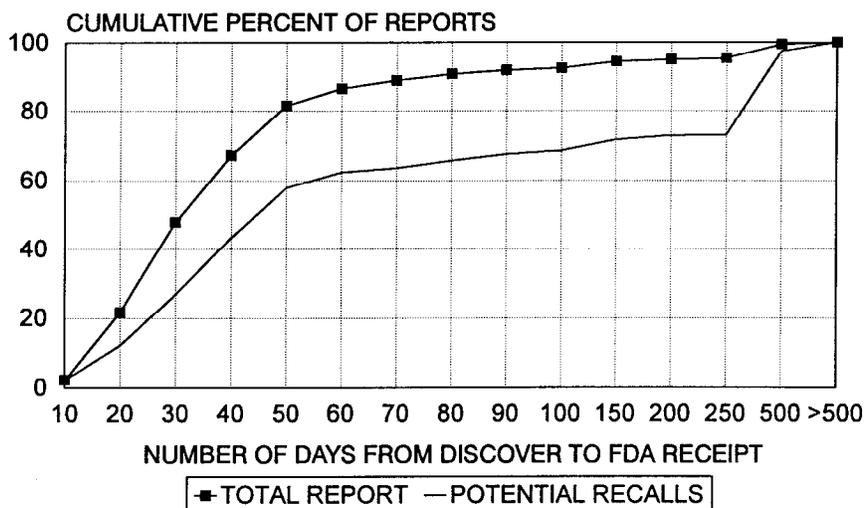
TOTAL REPORTS = 257  
POTENTIAL RECALLS = 14

## ERROR AND ACCIDENT REPORTS REPORTING TIME PLASMA CENTERS YEAR-TO-DATE FY98



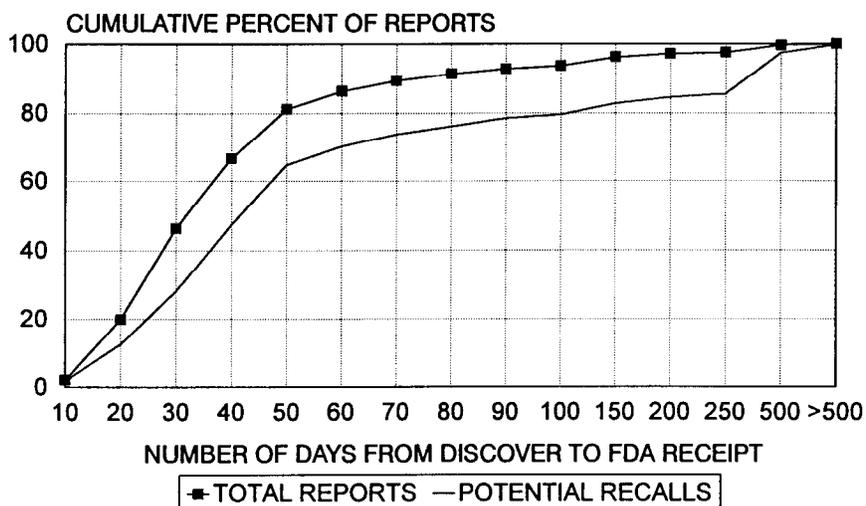
TOTAL REPORTS = 801  
POTENTIAL RECALLS = 64

## ERROR AND ACCIDENT REPORTS REPORTING TIME ALL LICENSED BLOOD BANKS THIRD QUARTER FY98



TOTAL REPORTS = 2766  
POTENTIAL RECALLS = 419

## ERROR AND ACCIDENT REPORTS REPORTING TIME ALL LICENSED BLOOD BANKS YEAR-TO-DATE FY98



TOTAL REPORTS = 8053  
POTENTIAL RECALLS = 1147